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RUEAUSA/DEPT OF HHS WASHDC
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UNCLAS SECTION 01 OF 03 NEW DELHI 002936

STATE FOR OES/PCI, OES/STC, OES/SAT, OES/EGC,
AND SCA/INS
STATE FOR STAS
STATE PASS TO NSF FOR INTERNATIONAL PROGRAMS
HHS PASS TO NIH
STATE PASS TO USAID
STATE FOR SCA, OES (STAS FEDOROFF), OES/PCI STEWART; OES/IHB MURPHY
PASS TO HHS/OGHA (STEIGER/ABDOO/VALDEZ), CDC (BLOUNT/FARRELL),
NIH/FIC (GLASS/MAMPILLY/HANDLEY),
FDA (LUMPKIN/WELSCH, GENEVA FOR HOFMAN)
PASS TO MAS/DAS/JESTRADA
PASS TO MAC/DAS/HVINEYARD

SIPDIS

E.O. 12958: N/A
TAGS: TBIO SENV AMED CASC KSCA ECON ETRD BEXP EINV PGOV
TSPL, TRGY, TNGD, EIND, ENRG, KGHG, IN

SUBJECT: NEW DELHI BI-WEEKLY ESTH REPORT: NOVEMBER 2008 FIRST WEEK

¶1. (U) SUMMARY: This edition of the New Delhi ESTH biweekly includes updates on the upcoming visit of the Nuclear Regulatory Commission delegation visit to India, the management of professional education in India and the opening of the UK Research Council's office in India and poaching incidents. The health section presents a dengue update, the U.S. Food and Drug Administration's (FDA) training on regulatory aspects of medical devices to officials in India, and its other engagements in India, including consultations on regulatory systems for genetically engineered organisms and key challenges in India.

Nuclear Regulatory Commission (NRC) Delegation Visit to India
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¶2. (U) The NRC delegation led by the Chairman Dr. Dale E. Klein is visiting India from 11 - 28 November 2008. During the course of the visit the NRC delegation will attend the International Atomic Energy Agency (IAEA) Conference on Nuclear Safety hosted by the Atomic Energy Regulatory Board (AERB), meet with officials in the Government of India (GOI), Department of Atomic Energy, representatives of the nuclear power industry and also visit the Kaiga Nuclear Power Station in Karnataka on November 21.

New Agencies to Monitor Higher and Professional Education

¶3. (U) There is a growing demand for reduction of ineffective

regulations and bodies in the field of higher education and professional education. Recently the National Knowledge Commission (NKC) and the Federation of Indian Chamber of Commerce and Industry (FICCI) had independently called for removing of agencies like the All Indian Council of Technical Education (AICTE) saying that they had become completely ineffective or even irrelevant and there is a need for more autonomy in higher education. The Administrative Reforms Committee's (ARC) Ninth report titled "Social Capital - a Shared Destiny" should be looked into in this context.

¶4. (U) The ARC is a commission set up by GOI in 2004 to prepare a detailed blueprint for revamping the public administration system in India. Mr. Veerappa Moily (former Chief Minister of Karnataka) as the Chairperson heads the six member committee of ARC formulated to carry out the directives of the commission. The committee has a mandate to suggest improvements of all aspects of governance. Reporting on the monitoring and management of the professional education in India, which till a decade ago, was primarily publicly funded and even now highly regulated by government bodies, has asked for the abolishing of the regulatory bodies like the AICTE. The ARC in its Ninth report titled "Social Capital - a Shared Destiny" released on 4 November 2008 has suggested that in place of bodies like AICTE, there should be new separate professional councils for different streams of professional education including engineering, medicine, management and pharmacy. The committee has further said that the councils should have full autonomy to lay down norms, standards and parameters related to individual fields for setting up of institutions, designing and updating curriculum, faculty improvement and research. One of the prominent recent GOI initiative based on the ARC reports was the reservation for backward classes in higher education. Hence one could expect changes to happen in the higher and professional education domain based on the new report.

UK Research Council Opens Shop in India

¶5. (U) The UK Research Council (RCUK) inaugurated its new office in India with a workshop attended by leading scientists from India and UK. The RCUK Office in India will work with Indian funding bodies to share strategies, increase dialogue on funding priorities and pursue and promote collaborative research opportunities. The office will also focus on developing strategic partnerships between scientific research institutes and business communities.

Tiger Update

¶6. (U) The Rajasthan Forest Department that oversaw the successful re-introduction of two tigers a few months back from Ranthambhore Tiger Reserve to Sariska Tiger Reserve is on the lookout for another young adult tigress to relocate to Sariska. However, poaching incidents continue and in separate incidents tigers in Sundarbans Tiger Reserve in West Bengal and Kanha Tiger Reserve were killed by poachers. In Sundarbans this is the first of its kind poaching incident in over fifteen years, however Kanha and other parks in Central India has seen a spate of poaching incidents over the last few years.

Dengue Update

¶7. (U) The Delhi-based National Institute of Communicable Diseases (NICD) has confirmed on November 3, 2008 that in India's State of Punjab, the Ludhiana district is the worst affected with a total number of dengue cases at 2,200, with six reported deaths. Other districts in Punjab affected are Amritsar, Bhatinda, Jullunder, and Patiala; however, these in comparison have fewer dengue cases than in Ludhiana. In Delhi, as of 26 October 2008 a total of 1,057 cases were reported, with 2 deaths. These numbers are for the National Capital Region of Delhi, including Gurgaon. Two other States

reporting dengue cases are West Bengal and Karnataka, but the case numbers are not significant.

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FDA Collaborates with India's Regulators on Medical Devices
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¶8. (U) The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), in collaboration with the Drugs Controller General (India) (DCGI) office, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India, organized the Medical Devices Workshop. Three FDA CDRH experts, Deputy Director for Regulatory Affairs Dr. Larry Spears, Associate Director for Policy and Operations Office of In Vitro Diagnostics Dr. Don St. Pierre, and Acting Deputy Director Division of Office of Compliance Dr. Erin Keith, provided training on regulatory aspects of medical devices to regulatory officials from the DCGI's office and State Drug Controllers in Delhi on 30-31 October 2008. Medical devices is one of six areas for U.S.-India collaborations with the DCGI's office. The other areas are

Structure of Central Drug Authority (CDA), E-Governance, Pharmacovigilance, Clinical Trials, and Regulation for High Technology Products. Workshop topics included an overview of FDA's mission and legislative mandates and appraised participants of FDA's establishment registration and medical device listing, quality systems, import and export requirements for medical devices, regulation of combination products, regulation of in vitro diagnostics, classification and pre-market notification, the pre-market approval process, investigational device exemptions, medical device reporting, medical device recall, and an introduction to enforcement inspections and regulatory actions. FDA experts will also speak at the 13th Asian Harmonization Working Party (AHWP) Pre-Meeting Workshop 3-4 November 2008 in New Delhi and attend the AHWP meeting from 5-6 November 2008. This meeting is being organized by the Federation of Indian Chambers of Commerce and Industry (FICCI) with support by the AHWP and India's Ministry of Health and Family Welfare.

International Consultation on National Biotechnology Regulatory Authority
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¶9. (U) U.S. FDA Center for Biologics Evaluation and Research (CBER) Director Dr. Jesse L. Goodman is participating in the international roundtable on the proposed National Biotechnology Regulatory Authority (NBRA) organized by the Department of Biotechnology, Ministry of Science and Technology, Government of India, from 3-4 November 2008 in New Delhi. The topics of the consultation include establishing and making operational Indian agencies and regulatory systems to regulate genetically engineered organisms and to address key challenges and share experiences. Experts from Australia, Canada, the European Union, the Philippines, and U.S. agencies such as FDA and APHIS are participating in the deliberations. Dr. Goodman will also meet with key officials of the Government of India.

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